Memoradum

Date: June 23, 2003

To: FDA Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC) members

Subject: Safety of bovine bone gelatin in oral and topical drugs, food and cosmetics

From: FDA Gelatin Planning Work Group

The FDA TSEAC will meet on Thursday and Friday, July 17 and 18, 2003 in Bethesda, MD. In the morning of the first day, safety of bovine bone gelatin in oral and topical drugs, food and cosmetics will be discussed.

The TSEAC in the past has discussed the safety of gelatin twice. During those meetings, Gelatin Manufacturers Europe presented reports of validation studies on the capability of the gelatin manufacturing processes to remove and/or inactivate TSE agents. The Committee concluded those studies were not conducted properly and requested additional studies to be performed. The new studies have been completed and are ready to be presented to the Committee. In addition to a report of these new validation studies, other relevant marketing and manufacturing information on gelatin will be presented. Committee will be asked to discuss and vote on several questions from FDA.

The questions and background materials for this topic are attached.